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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,103	10/03/2005	Hartmut Schlucter	Merk-3002	9112
23599 7590 07/16/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER THERKORN, ERNEST G				
ART UNIT		PAPER NUMBER		
1797				
NOTIFICATION DATE		DELIVERY MODE		
07/16/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary

Application No.

10/528,103

Applicant(s)

SCHLUETER, HARTMUT

Examiner

Ernest G. Therborn

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claims 1-6 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Mikes' Laboratory Handbook of Chromatographic and Allied Methods, John Wiley&Sons, New York, 1979, pages 35-40 is relied upon as evidence by the examiner. Applicant is relying on the instant specification's use of the term "eluate" to support the phrases "elution chromatography" and "whereby suitable elution chromatography parameters for separating the biological into biomolecules are ascertained". Applicant is also relying upon paragraph 5 of the primary reference, Cramer (U.S. Patent Publication No. 2001/0047086), for a distinction between elution chromatography and displacement chromatography. It is clear from the first sentence of paragraph 6 of Cramer (U.S. Patent Publication No. 2001/0047086) that displacement chromatography uses an eluant. Displacement chromatography differs from elution chromatography in that the eluant contains a displacer. Thus, the fact that applicant's specification uses the term "eluates" is equally supportive of both elution and displacement chromatography. As such, there is no support in the specification for precluding displacement chromatography. This is particularly true because page 4, line 28; page 6, line 28; page 21, lines 24 and 27; and page 26, lines 2, 3, and 16 of applicant's specification specifically discloses that applicant's invention is directed to displacement chromatography. The phrases "elution chromatography" and

"whereby suitable elution chromatography parameters for separating the biological into biomolecules are ascertained" are drawn to new matter because they are being used to preclude displacement chromatography and the instant specification does not have any support for precluding displacement chromatography. Accordingly, the claims are considered to be drawn to new matter. Applicant appears to urge that gradient chromatography is synonymous with elution chromatography. However, Mikes' Laboratory Handbook of Chromatographic and Allied Methods, John Wiley&Sons, New York, 1979, pages 35-40 on pages 38-40 evidences that elution chromatography includes simple elution (isocratic elution), stepwise elution, and gradient elution. As such, gradient chromatography is not considered to be synonymous with elution chromatography.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 10 are rejected under 35 U.S.C. 102(B and/or E) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cramer (U.S. Patent Publication No. 2001/0047086). The claims are considered to read on Cramer (U.S. Patent Publication No. 2001/0047086). The preamble of claim 1 is directed to "discovering chromatography parameters." Many of the parameters that Cramer (U.S. Patent Publication No. 2001/0047086) uses are equally applicable to both "elution chromatography" and "displacement chromatography." These parameters would include the last line of Cramer (U.S. Patent Publication No. 2001/0047086)'s Abstract such as "different stationary phase materials, biomolecules, and modes of interaction." This would include Cramer (U.S. Patent Publication No. 2001/0047086)'s penultimate sentence of paragraph 9 of "the identification of important properties for a particular interaction or for similar interactions on different stationary phases." This would include Cramer (U.S. Patent Publication No. 2001/0047086)'s paragraphs 18 and 33 "determining the equilibrium concentration of the bioproduct." As such, Cramer (U.S. Patent Publication No. 2001/0047086) discloses "discovering suitable elution chromatograph parameters." The preamble of claim 1 is also directed to an automated method. This is disclosed in Cramer (U.S. Patent Publication No. 2001/0047086) on paragraph 53, particularly lines 4-6. Claim 1, step a is disclosed in the last four lines of paragraph 30 of Cramer (U.S. Patent Publication No. 2001/0047086) and in Figure 1. Claim 1, step b is disclosed in paragraphs 17 and 33 of Cramer (U.S. Patent Publication No. 2001/0047086). Claim 1, step c's different chromatographic parameters is

disclosed in the last sentence of the Abstract and the penultimate sentence of paragraph 9 of Cramer (U.S. Patent Publication No. 2001/0047086). Claim 1, steps d and e's separation and analysis is disclosed in paragraph 18 of Cramer (U.S. Patent Publication No. 2001/0047086). The ascertaining of parameters is disclosed in Cramer (U.S. Patent Publication No. 2001/0047086) in the last three lines of the Abstract, the penultimate sentence of paragraph 9, paragraphs 16-18, and paragraph 33. However, if a difference exists between the claims and Cramer (U.S. Patent Publication No. 2001/0047086), it would reside in optimizing the steps of Cramer (U.S. Patent Publication No. 2001/0047086). It would have been obvious to optimize the steps of Cramer (U.S. Patent Publication No. 2001/0047086) to enhance separation.

Claims 1-6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160). At best, the claims differ from Cramer (U.S. Patent Publication No. 2001/0047086) in reciting elution chromatography. Welch (U.S. Patent No. 6,342,160) (Figure 15, column 3, lines 15-17, column 2, lines 24-35, column 3, lines 38-40, and column 6, line 50 and 65-67) discloses that use of an array of different media with sample allows for the selection of a highly selective adsorbent for a given separation problem. It would have been obvious that Cramer (U.S. Patent Publication No. 2001/0047086)'s method would reveal suitable elution chromatography parameters because Welch (U.S. Patent No. 6,342,160) (Figure 15, column 3, lines 15-17, column 2, lines 24-35, column 3, lines 38-40, and column 6, line 50 and 65-67) discloses that

use of an array of different media with sample allows for the selection of a highly selective adsorbent for a given separation problem.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Cramer (U.S. Patent Publication No. 2001/0047086) alone or Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160) as applied to claims 1-6 and 10 above, and further in view of each of MacPhee (U.S. Patent No. 2003/0161753), Snyder (U.S. Patent Publication No. 2005/0182242), and Pantoliano (U.S. Patent No. 6,214,293). At best, the claim differs from either Cramer (U.S. Patent Publication No. 2001/0047086) alone or Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160) in reciting use of a stabilizer. MacPhee (U.S. Patent No. 2003/0161753) (paragraph 38, lines 3, 19, 20, and 32) discloses stabilizing biological materials with glycerol reduces damage to the biological material. Snyder (U.S. Patent Publication No. 2005/0182242) (paragraphs 120 and 121) discloses that glycerol stabilizes protein. Pantoliano (U.S. Patent No. 6,214,293) (column 6, lines 11-24 and column 57, lines 25-31) discloses glycerol stabilizes protein. It would have been obvious to use a stabilizer in either Cramer (U.S. Patent Publication No. 2001/0047086) alone or Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160) because MacPhee (U.S. Patent No. 2003/0161753) (paragraph 38, lines 3, 19, 20, and 32) discloses stabilizing biological materials with glycerol reduces damage to the biological material. It would have been obvious to use a stabilizer in either Cramer (U.S. Patent Publication No. 2001/0047086) or Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch

(U.S. Patent No. 6,342,160) because Snyder (U.S. Patent Publication No. 2005/0182242) (paragraphs 120 and 121) discloses that glycerol stabilizes protein. It would have been obvious to use a stabilizer in either Cramer (U.S. Patent Publication No. 2001/0047086) or Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160) because Pantoliano (U.S. Patent No. 6,214,293) (column 6, lines 11-24 and column 57, lines 25-31) discloses glycerol stabilizes protein.

Claims 1-6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160) and Mikes' Laboratory Handbook of Chromatographic and Allied Methods, John Wiley&Sons, New York, 1979, pages 35-40. At best, the claims differ from Cramer (U.S. Patent Publication No. 2001/0047086) in reciting elution chromatography. Welch (U.S. Patent No. 6,342,160) (Figure 15, column 3, lines 15-17, column 2, lines 24-35, column 3, lines 38-40, and column 6, line 50 and 65-67) discloses that use of an array of different media with sample allows for the selection of a highly selective adsorbent for a given separation problem. Mikes' Laboratory Handbook of Chromatographic and Allied Methods, John Wiley&Sons, New York, 1979, pages 35-40 is relied upon as evidence for the definition of displacement and elution chromatography. For example, Mikes' Laboratory Handbook of Chromatographic and Allied Methods, John Wiley&Sons, New York, 1979, pages 35-40 on pages 38-40 evidences that elution chromatography includes simple elution (isocratic), stepwise elution, and gradient elution. As such, gradient chromatography is not considered to be synonymous with elution chromatography. It would have been obvious that Cramer

(U.S. Patent Publication No. 2001/0047086)'s method would reveal suitable elution chromatography parameters because Welch (U.S. Patent No. 6,342,160) (Figure 15, column 3, lines 15-17, column 2, lines 24-35, column 3, lines 38-40, and column 6, line 50 and 65-67) discloses that use of an array of different media with sample allows for the selection of a highly selective adsorbent for a given separation problem.

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Methods, John Wiley&Sons, New York, 1979, pages 35-40 because MacPhee (U.S. Patent No. 2003/0161753) (paragraph 38, lines 3, 19, 20, and 32) discloses stabilizing biological materials with glycerol reduces damage to the biological material. It would have been obvious to use a stabilizer in Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160) and Mikes' Laboratory Handbook of Chromatographic and Allied Methods, John Wiley&Sons, New York, 1979, pages 35-40 because Snyder (U.S. Patent Publication No. 2005/0182242) (paragraphs 120 and 121) discloses that glycerol stabilizes protein. It would have been obvious to use a stabilizer in Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160) and Mikes' Laboratory Handbook of Chromatographic and Allied Methods, John Wiley&Sons, New York, 1979, pages 35-40 because Pantoliano (U.S. Patent No. 6,214,293) (column 6, lines 11-24 and column 57, lines 25-31) discloses glycerol stabilizes protein.

Applicant urges the phrases "elution chromatography" and "whereby suitable elution chromatography parameters for separating the biological into biomolecules are ascertained" are supported because the term "eluates" is used in the specification. However, applicant is relying upon paragraph 5 of the primary reference, Cramer (U.S. Patent Publication No. 2001/0047086), for a distinction between elution chromatography and displacement chromatography. It is clear from the first sentence of paragraph 6 of Cramer (U.S. Patent Publication No. 2001/0047086) that displacement chromatography uses an eluant. Displacement chromatography differs from elution chromatography in that the eluant contains a displacer. Thus, the fact that applicant's specification uses

the term "eluates" is equally supportive of both elution and displacement chromatography. As such, there is no support in the specification for precluding displacement chromatography. The phrases "elution chromatography" and "whereby suitable elution chromatography parameters for separating the biological into biomolecules are ascertained" are drawn to new matter because they are being used to preclude displacement chromatography and the instant specification does not have any support for precluding displacement chromatography. This is particularly true because page 4, line 28; page 6, line 28; page 21, lines 24 and 27; and page 26, lines 2, 3, and 16 of applicant's specification specifically discloses that applicant's invention is directed to displacement chromatography.

Applicant appears to urge that gradient chromatography is synonymous with elution chromatography. However, Mikes' Laboratory Handbook of Chromatographic and Allied Methods, John Wiley&Sons, New York, 1979, pages 35-40 on pages 38-40 evidences that elution chromatography includes simple elution (isocratic), stepwise elution, and gradient elution. As such, gradient chromatography is not considered to be synonymous with elution chromatography.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernest G. Therkorn/
Ernest G. Therkorn
Primary Examiner
Art Unit 1797

EGT
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